DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 7, 2014

William A. Cook Australia Pty, Ltd.
Katie-Lou Buscher
Project Manager, Regulatory Affairs
95 Brandl Street
Brisbane Technology Park, Eight Mile Plains
Brisbane, QLD 4113
AUSTRALIA

Re: K141365
Trade/Device Name: Otrieva™ Tapered Ovum Aspiration Needle
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: July 14, 2014
Received: July 15, 2014

Dear Katie-Lou Buscher,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141365

Device Name
Otrieva™ Tapered Ovum Aspiration Needle

Indications for Use *(Describe)*
The Cook Otrieva™ Tapered Ovum Aspiration Needles are used for laproscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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WILLIAM A. COOK AUSTRALIA PTY. LTD.
95 BRANDL STREET
BRISBANE TECHNOLOGY PARK, EIGHT MILE PLAINS
BRISBANE, QLD 4113, AUSTRALIA
PHONE: 1800.777.222 FAX: +61.7.3841.1288
WWW.COOKMEDICAL.COM
ABN 79 005 526 723

510(k) Summary - K141365
Otrieva™ Tapered Ovum Aspiration Needle – 14 July 2014

Submitted by:

William A. Cook Australia
95 Brandl Street
Eight Mile Plains
Brisbane
Queensland
4113
Australia

Contact: Katie-Lou Buscher
Email: Katie-Lou.Buscher@CookMedical.com
Telephone: +61 7 3841 1188
Fax: +61 7 3841 1288

Trade name Otrieva™ Tapered Ovum Aspiration Needle

510(k) Number K141365

Classification name Assisted Reproduction Needles (21 CFR 884.6100, Product Code MQE)

Predicate Device Ovum Pick-Up Aspiration Needle, cleared under K983593

Device Description This device is intended for laparoscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles

The needle is passed through a transvaginal ultrasound transducer or placed through a cannula for a laparoscopic procedure to advance into the ovarian follicle.

The main body of the cannula is 17 gage, which tapers to 20 gage at the distal tip. Although the outer diameter of the needle tapers, a constant 0.60 mm internal diameter is maintained.

The Otrieva™ needles are available in two lengths: 30cm and 35cm. The needles are provided with an aspiration tube of 90 cm length and a vacuum tube with a length of 50 cm. The tubing is connected to a silicone bung.

The materials used in the device include: stainless steel, polycarbonate, PTFE, silicone, FEP and copolyester.

Indication for Use The Cook Otrieva™ Tapered Ovum Aspiration Needles are used for laparoscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles.

Comparison to Predicate Device

The Otrieva™ Tapered Ovum Aspiration Needle is a modification of the Ovum Pick-up Aspiration Needle (K983593). The modifications are:

- Incorporation of a tapered cannula instead of fixed diameter cannula - the tapered cannula is designed to allow the clinician the rigidity of a larger diameter cannula while providing a smaller diameter tip for puncture. As the inner and outer diameter of the cannula at both ends falls within the range of the predicate device, and the internal lumen of the cannula is the same as the predicate device, this change does not represent a new technology that could raise new types of safety or effectiveness questions.

- Addition of a 50 cm vacuum line - the addition of the vacuum line simply provides an extension of the connection to the vacuum source and does not change the use of the device. Attachment of an Ovum Aspiration Needle to the vacuum source using tubing is not a new technology and therefore there are no new safety or effectiveness questions raised.

- Incorporation of a smaller (1.32 mm) diameter aspiration tube – The smaller diameter aspiration tube is applied to better match the inner lumen of the needle cannula. This modification is not a new technology and does not raise new types of safety or effectiveness questions.

In addition to the modifications described above, the Indication for Use statement has been modified from the predicate device to include transvaginal ultrasound and laparoscopic approaches, both of which were specifically stated within the instructions for the predicate device, just not stated directly within the Indications for Use statement. This modification to the Indication for Use statement does not impact safety and efficacy of the device.

The Mouse Embryo Assay (MEA) specification has changed from one-cell (75% or greater blastocyst rate at 96 h) to 2-cell (80% or greater blastocyst rate at 72 h). This is a change in performance specification, and does not represent a new technology, therefore the safety and effectiveness is not altered.

A full comparison is provided in Table 1 over the page.

510(k) Summary - K141365
Otrieva™ Tapered Ovum Aspiration Needle – 14 July 2014

Table 1 - Comparison of Otrieva and predicate device

Device Name	**Otrieva™ Tapered Ovum Aspiration Needle**	**Ovum Pick-Up Aspiration Needle**	**Comparison**
Indication for Use	The Cook Otrieva™ Tapered Ovum Aspiration Needles are used for laparoscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles.	The Ovum Pick-Up Aspiration Needles are used for aspiration and flushing of oocytes from ovarian follicles.	The Otrieva Indication for Use has the addition of ultrasound and laparoscopic approaches explicitly stated. The predicate device is intended to be used laparoscopically and with transvaginal ultrasound, as described in the predicate 510(k) summary, and these approaches were also included in the cleared labelling for the predicate device. This is not a new intended use, as the clinical practise has always included transvaginal ultrasound and laparoscopy.
Contraindications	This device should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, a recent uterine perforation, a recent caesarean section, or who is currently pregnant.	This device should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, or who is currently pregnant.	These patient populations were added to ensure consistency with clinical practices for in *vitro* fertilization.
Product Description	Needle passed through transvaginal ultrasound transducer or placed through a cannula for a laparoscopic procedure to advance into the ovarian follicle.	Needle passed through transvaginal ultrasound transducer or placed through a cannula for a laparoscopic procedure to advance into the ovarian follicle.	The description of the Otrieva™ is substantially equivalent to the predicate device.
Dimensions			
Gage	17 G tapering to 20 G	12 G – 20 G	The Otrieva™ Tapered Ovum Aspiration Needle has an increased wall thickness at the 17 G proximal portion of the needle cannula which is necessary to ensure an appropriate wall thickness at the distal, tapered end of the needle while maintaining a 0.60 mm inner diameter.
Cannula Inner Diameter	0.60 mm	2.10 mm – 0.60 mm	
Needle Length	30 & 35 cm	20 cm - 40 cm	
Aspiration Tubing Length	90 cm	25cm - 90 cm	

510(k) Summary - K141365
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Device Name	Otrieva™ Tapered Ovum Aspiration Needle	Ovum Pick-Up Aspiration Needle	Comparison
Aspiration Tubing External Diameter	1.32 mm	1.67 mm – 2.7 mm (5 Fr – 8 Fr)	The diameter of the Otrieva aspiration tubing is smaller than the predicate.
Vacuum Tubing Length	50 cm	N/A	Vacuum tubing has been added to the design of the Otrieva™ Tapered Ovum Aspiration Needle
Vacuum Tubing External Diameter	2.06 mm	N/A	
Materials			
Needle Cannula	Stainless Steel #304	Stainless Steel #304	Same
Needle Hub	Polycarbonate	Polycarbonate	Same
Aspiration Tubing	PTFE	PTFE	Same
Vacuum Tubing	FEP	N/A	Vacuum tubing has been added to the design of the Otrieva™ Tapered Ovum Aspiration Needle
Test Tube Stopper	Silicone	Silicone	Same
Vacuum Line Female Conical Fitting	Copolyester or Polycarbonate	N/A	Vacuum tubing has been added to the design of the Otrieva™ Tapered Ovum Aspiration Needle
Vacuum Line Cannula	Stainless steel #304	Stainless steel #304	Same
Other characteristics			
Lumens	Single	Single or Double	Otrieva™ Tapered Ovum Aspiration Needle lumen type falls within the range of the predicate device
Echo-tip	Echo-Tip only	With or without Echo-Tip	Otrieva™ Tapered Ovum Aspiration Needle lumen type falls within the range of the predicate device
Shelf Life	3 years	3 years	Same
Single Use/Reusable	Single Use	Single Use	Same
Sterility	Sterile (SAL 10^{-6})	Sterile (SAL 10^{-6})	Same
Endotoxin Specification	USP endotoxin (LAL) tested and passed with 20EU or less per device	USP Endotoxin (LAL) tested and passed with 20EU or less per device	Same
MEA specification	Two-cell MEA tested and passed with 80% or greater Blastocyst rate at 72h.	Once cell MEA tested and passed with 75% or greater Blastocyst at 96 h.	MEA test has changed from 1-cell MEA (75% or greater Blastocyst at 96 h) to 2-cell MEA (80% or greater Blastocyst at 72 h). Both techniques are acceptable and provide indication of embryo toxicity.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Packaging	Polyester/low density polyethylene film with Tyvek backing.	Tyvek-Poly pouch	Same

Non-clinical testing summary

The Otrieva™ Tapered Ovum Aspiration Needle has undergone non-clinical testing to verify the design modifications did not affect the performance of the needle. The testing included

- Resistance to breakage testing
- Air tightness testing
- Tensile strength testing between the tubing and handle junction
- Leakage testing

The design modifications were shown to have no adverse effect on the needle performance in any of these tests.

Safety and Efficacy

The results of the testing provide reasonable assurance that the Otrieva™ Tapered Ovum Aspiration Needle is as safe and effective as the predicate device and support a determination of substantial equivalence.